a remotely-controlled transmitter means in communication with said controller unit, said transmitter means generating a transmitter alarm signal in respond to said outgoing alarm signal from said controller unit; and

alarm generation means selected from the group consisting of a vibration device releasably disposed on the patient's torso, a vibration device releasably attached on the patient's extremity, an audio device movably located proximal to the patient, and an audio device removably attachable to the patient's head.

24. The system of claim 1 [23] further including a humidifier.

REMARKS

In contrast to the prior art, Applicant' invention is designed to detect gross leaks, and directed to solve the frequent problem of the mask being removed from the patient's face while sleeping. When the mask is removed, the patient obviously is not receiving the necessary respiratory therapy for his sleep disorder. Therefore, it is Applicant's goal to sense when the mask has been removed and to alert the patient without arousing those sleeping with or near the patient.

The prior art does not attempt to solve the same problem as Applicant. In fact, Froehlich does attempt to detect "excessive mask leaks" and instances of mouth-breathing, but its algorithm is designed to ignore gross leaks and compensate for mouth-breathing by adjusting the output of the CPAP generator. [See e.g. Froehlich Col. 3 lines 15-33; "If a leak above a threshold level is detected, the algorithm *ignores* events that are scored until the leak level drops below the threshold."] Instead, Froehlich suggests selecting a different size or style mask such as one with a chin strap to avoid the problem of the mask being removed.

Truschel is also directed to sensing when a low leak has occurred by determining whether the flow is below an alarm threshold. Truschel is concerned with detecting when the exhaust port is completely or partially blocked by secretions from the patient or by sheets and pillows being used by the patient. As shown in the flow chart in Fig. 5, the low leak alarm is triggered when the leak is less than the threshold for one minute. Another goal of the Truschel system is to allow for other conditions which affect the air flow, such as the introduction of a supplemental breathing gas, e.g. oxygen into the system and not produce a false alarm. [Col 3, lines 25-30].

Servidio discloses a CPAP system which is intended to solve the problem of audible noise associated with varying the speed of the blower and to resolve problems encountered by bi-level blowers. Servidio discloses a system with a pressure regulator valve 150 placed between the patient mask and the flow sensor 252, the valve modulating pressure to the patient. As stated by Servidio: "Since the flow sensor in this location cannot sense expiration flows, the device includes circuitry for generating a model of the expiratory waveform." [Abstract, last sentence]. Although Servidio does state: "A patient alarm may occur during the normal operation if high flows persist, indicating the patient's mask is off." [Col. 9, lines 60-67], Servidio does not suggest the solution claimed by Applicant to utilize the measurements of the air flow to and from the patient as well as a pressure sensor. The system in Servidio is not capable of sensing how much air is being exhaled from the patient. Consequently, if the patient's mask is partially askew during sleep, the system in Servidio would be unable to detect that fact. In Applicant's system, because Applicant is monitoring three variables, including the amount of exhalation, Applicant's system can alert the patient that his mask is not fully in place. (Further, Applicant's system claimed invention provides for silent alert and is wireless.)

INTERVIEW WITH THE EXAMINER

Applicant's counsel and the Examiner conducted a telephone interview on December 20, 2005 and discussed the fact that at least three separate searches have now been conducted: two by the Examiner and one by the Applicant. The Examiner's searches included the subject matter claimed in the originally filed claims, including claims 1, 13, 14 and 16. Initially filed claim 1 included all systems which use the measured air flow to and from the patient and a pressure sensor to alert the patient to conditions including that the mask is not properly in place. Claims 13, 14 and 16 specify that the system alerts the patient when the mask in not properly in place around the patient's face. Therefore, it is believed that further searching is not required for the substantially narrowed claims now pending.

None of the prior art systems attempt to solve the problems of (1) patient mask removal by triggering an alarm which alerts only the patient without disturbing others and (2) the inconvenience of having wires interconnecting the critical components. Further, applicant's invention is intended to be easily retrofitted into the numerous existing CPAP systems which do not have either the silent alarm generation upon mask removal or the wireless transmission. As stated in Applicant's specification: "At least one of the numerous benefits of the notification system 10 and method for notification can be readily added to preexisting CPAP generator units 12 by interconnecting the air flow sensors 20 and/or pressure sensor 50, along with the additional controller, transmitter and alarm means 22, 40, 44, 44", 46, 48. Therefore, preexisting CPAP generator units 12 can be improved by the addition of the notification system 10 and utilization of the method for notification in order for one skilled in the art to maximize the treatment with preexisting CPAP generator units 12 for sleep apnea and other sleep disorders of the patient." [paragraph 0030].

An advisory action is respectfully requested and a further telephone interview if deemed appropriate by the Examiner.

Dated: December 20, 2005

Respectfully submitted,

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